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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,814	06/13/2001	Andrea Buchacher	P66014US1	4216

7590

10/02/2002

LAW OFFICES OF  
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WASHINGTON, DC 20004

EXAMINER

MAYES, LAURIE A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/879,814

Applicant(s)

BUCHACHER ET AL.

Examiner

Laurie Mayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The two abstracts listed in the "OTHER DOCUMENTS" section of the information disclosure statement, XP-002116643 and XP-002116642, are incomplete citations. The applicant must submit an information disclosure statement with the actual citations.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim recites the limitation "the clotting cascade". There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-20, 22-23 and 25-26 rejected under 35 U.S.C. 102(b) as being anticipated by Bloomingburg. (paper #6), The reference describes a process for the separation or isolation of plasma proteins from a mixture containing plasma proteins where the mixture is applied to a separation medium with an annular design (p. 1062, col. 1, line 2 and lines 14-15) with a layer of

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application medium on the separation medium, namely, Dowex Monosphere from Dow Chemical Co. (p. 1062, col. 1, lines 10-12), where the separation medium is rotated vertically about an axis which is defined in the direction of flow of the mixture through the separation medium (p. 1062, col. 1, line 5), where an eluent is passed through the separation medium (p. 1062, col. 1, lines 17-20) and where fractions exit at the end of the separation medium (p. 1062, col. 1, line 17). Thus Bloomingburg reasonably appears to teach or describe every element of claim 14. Therefore, Bloomingburg anticipates claim 14 within the meaning of 35 U.S.C. section 102(b).

Bloomingburg also describes the above-mentioned process wherein the application medium has spherical particles (p. 1062, col. 2, line 11) and has a treated surface which prevents non-specific interactions with components to be separated from the mixture (p. 1062, col. 1, line 12), and wherein the mixture is blood plasma (p. 1061, col. 2, line 14) and has at least two plasma proteins, namely, albumin and hemoglobin and albumin and cytochrome c (p. 1062, col. 1, lines 33-34). Since Bloomingburg reasonably appears to teach or describe every element of claims 15-18, the reference anticipates claims these claims within the meaning of 35 U.S.C. section 102(b).

Further, Bloomingburg also describes a process wherein the separation medium is used for molecular size exclusion or chromatography based where only a small fraction of the total water content of the resin beads is freely accessible by the proteins (p. 1063, col. 1. last line and col. 2, lines 1-2), where the separation medium is continuously regenerated and equilibrated simultaneously with the separation of the plasma proteins (p. 1062, col. 1, lines 17-30), where at least two separation media are used in layers, namely, S Sepharose from Pharmacia and Dowex

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Monosphere (p. 1061, col. 2, lines 14-15 and p. 1062, col. 1, line 9), and where the separation medium is a polymeric block material, namely, Dowex Monosphere (p. 1062, col. 1, line 9). ). Thus Bloomingburg reasonably appears to teach or describe every element of claims 19, 23 and 24-26, and therefore Bloomingburg anticipates the claims within the meaning of 35 U.S.C. section 102(b).

Bloomingburg describes the process wherein the plasma proteins are human serum albumin (p. 1062, col. 1, line 33) and where the mixing, separating and fractioning of the plasma proteins are performed continuously (p. 1061, col. 1, last paragraph and p. 1062, col. 1, line 17). Thus Bloomingburg reasonably appears to teach or describe every element of claims 20 and 22, and Bloomingburg anticipates these claims within the meaning of 35 U.S.C. section 102(b).

Claims 14, 16, 17, 18, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (United States Patent Number 5,639,376). Lee describes a process for the separation or isolation of plasma proteins from a mixture containing plasma proteins where the mixture is applied to a separation medium with an annular design (p. 3, paragraph 2 and p. 7, para. 11) with a layer of application medium on the separation medium (p. 7, para. 12-13 and p. 8, para. 18), where the separation medium is rotated vertically about an axis which is defined in the direction of flow of the mixture through the separation medium (p. 7, para. 11 and p. 10, para. 36), where an eluent is passed through the separation medium (p. 10, para. 38), where fractions exit at the end of the separation medium (p. 10, para. 36), where there is a treated surface to prevent non-specific interactions (p. 4, para. 14), where the mixture is blood plasma (p. 4, para. 11), where the mixture contains at least two plasma proteins (p. 4, para. 13), where the plasma proteins are Factor VIII (p. 8, para. 15), and where there are at least two different

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separation media in layers (p. 10, para. 36). Thus Lee reasonably appears to teach or describe every element of claims 1, 16, 17, 18, 21 and 25 and therefore Lee anticipates these claims within the meaning of 35 U.S.C. section 102(b).

Claims 1, 18 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. (paper #6). Takahashi describes a process for the separation or isolation of plasma proteins from a mixture containing plasma proteins where the mixture is applied to a separation medium with an annular design (p. 403, col. 2, last paragraph) with a layer of application medium on the separation medium (p. 403, col. 2, last paragraph), where the separation medium is rotated vertically about an axis which is defined in the direction of flow of the mixture through the separation medium (p. 404, fig. 1), where an eluent is passed through the separation medium (p. 404, col. 1, lines 6-18), where fractions exit at the end of the separation medium (p. 404, fig. 1 and col. 1, lines 12-24), where hemoglobin and myoglobin are separated (p. 405, col. 2, para. 1 and 2), and where at least two different eluents are simultaneously passed through the separation medium (p. 403, col. 2, lines 2-15). Since Takahashi reasonably appears to teach or describe every element of claim 21, this claim is anticipated within the meaning of 35 U.S.C. section 102(b).

### **Conclusion**

**No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 7 AM to 3:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 305-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

*L. Mayes*  
Laurie Mayes  
Patent Examiner  
Art Unit 1653  
September 30, 2002

*Christopher S. F. Low*  
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